AUG 2 6 2003

K030440

OASYS –ORAL AIRWAY SYSTEM

Mark Abramson
35 Renato Court
Redwood City, CA 94061

Non-Confidential Summary of Safety and Effectiveness

April 16, 2003

Mark Abramson
35 Renato Court
Redwood City, CA 94061

Tel-(650) 369-9227

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Official Contact:	Mark Abramson, D.D.S.
Proprietary or Trade Name:	OASYS -Oral Airway System
Common/Usual Name:	Oral Appliance – anti-snoring device
Device:	OASYS -Oral Airway System
Predicate Devices:	Dr. Keith Thorton - K972061 Snore-Ezzer, LLC – K963063 Marketing Technologies, Inc. – K963616 Nellcor Puritan Bennett, Inc. - K962516

Device Description:

The OASYS ORAL AIRWAY SYSTEM Anti-Snoring Device is composed of:

- Lower tray fitted over the lower teeth.
- Upper shield fitting in front of upper anterior teeth.
- Upper molded splint fitted over upper teeth.
- Connecting mechanism joining upper shield and lower tray.
- **Extensions off shield which act as nasal dilators**

Intended Use:

Indicated use:	The OASYS Oral Airway System is intended to reduce or alleviate snoring and obstructive sleep apnea, OSA.
Target population:	Adult patients.

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Environment of Use: Home and sleep laboratories

Comparison to Predicate Devices:

Attribute	OASYS K030440	Breathe EZ K022891	Dr. 's Mouthpiece K991948	Marketing T.I. k963063
Use:				
Intended as an intraoral device	Yes	Yes	Yes	Yes
Intended to reduce or help snoring	Yes	Yes	Yes	Yes
Indicated for use with persons who snore	Yes	Yes	Yes	Yes
Indicated for single patient Multi-use	Yes	Yes	Yes	Yes
Indicated for use at home or sleep laboratories	Yes	Yes	Yes	Yes
Design:				
Heat sensitive impressible material for fitting to teeth	Yes	Yes	Yes	Yes
Custom fit for each user	Yes	Yes	Yes	Yes
Can be adjusted or Refit	Yes	Yes	Yes	Yes
Placed in users mouth each evening	Yes	Yes	Yes	Yes
Cleaned daily	Yes	Yes	Yes	Yes
Easily removed from Mouth Permits user to breath Through mouth	Yes	Yes	Yes	Yes

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Attribute	OASYS	Breathe EZ	Dr. 's Mouthpiece K991948	Marketing T.I. k963063
Prevents grinding of Teeth	Yes	Yes	Yes	Yes
Materials:				
Heat sensitive Impression material	Yes	Yes	Yes	Yes
Rigid tray	Yes	Yes	Yes	Yes
Non-Sterile	Yes	Yes	Yes	Yes

Difference Between Other Legally Marketed Predicated Devices

The difference between the intended device and predicates is only the design of the device. All of the predicates act as mandibular repositioners. **The OASYS has extensions which act as nasal dilators.** This difference does not have a significant effect on the safety or effectiveness of the device.

Literature supports the historical significance of oral devices that reposition the mandible and reduce and manage snoring as well as sleep apnea.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2003

Dr. Mark Abramson
Mark Abramson, D.D.S. Incorporated
35 Renato Court
Redwood City, California 94061

Re: K030440
Trade/Device Name: Oasys Oral Airway System
Regulation Number: 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK, LWF
Dated: July 8, 2003
Received: July 8, 2003

Dear Dr. Abramson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030440

Device Name: OASYS Oral Airway System

Indications For Use:

OASYS Oral Airway System is intended for use to reduce or eleviate snoring and obstructive sleep apnea.

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030440

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)